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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,625	03/09/2001	Elizabeth A. Wang	5160C-CON	2656

7590 05/17/2004  
FINNEGAN, HENDERSON, FARABOW  
GARRETT AND DUNNER, LLP  
1300 I STREET, N.W.  
WASHINGTON, DC 20005-3315

EXAMINER

ROMEO, DAVID S

ART UNIT PAPER NUMBER

1647

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/804,625

Applicant(s)

WANG ET AL.

Examiner

David S Romeo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 02/09/2004.
- 2a)  This action is **FINAL**.                      2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 24-26, 29, 30, 33, 35, 36, 38, 39, 41 and 42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_\_ is/are allowed.
- 6)  Claim(s) 24-26, 29, 30, 33, 35, 36, 38, 39 and 42 is/are rejected.
- 7)  Claim(s) 41 is/are objected to.
- 8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a)  All    b)  Some \*    c)  None of:
- Certified copies of the priority documents have been received.
  - Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_\_

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**DETAILED ACTION**

The amendment filed 02/09/2004 has been entered. Claims 24, 25, 26, 29, 30, 33, 35, 36, 38, 39, 41, 42 are pending. Claim 41 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) to the extent that it is drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12. Claims 24, 25, 26, 29, 30, 33, 35, 36, 38, 39, 41, 42 are being examined to the extent that they read upon the elected invention.

The terminal disclaimer filed on 02/09/2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,013,649 has been reviewed and is accepted. The terminal disclaimer has been recorded.

***Claim Rejections - 35 USC § 112***

Claims 33, 36, 39, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim(s) 33, 36, 39, 42 are indefinite over the recitation of "stringent conditions." Applicants argue that stringent hybridization conditions are defined in the specification at page 23, lines 25-27, and that stringent conditions are defined by Maniatis. Applicant's arguments have been fully considered but they are not persuasive. The specification at page 23, lines 25-27, discloses one set of hybridization conditions, and, as noted in the last Office action, stringency varies according to the hybridization conditions and the particular hybrid under study. It is unclear what conditions are intended. If Applicants intend the term "stringent hybridization conditions" to only encompass those conditions set forth at page 23,

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lines 25-27, of the present specification, then Applicants should not hesitate in amending the claims to recite those conditions.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for  
5 failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 42 is indefinite over the recitation of "BMP-2 protein." Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "BMP-2 protein" an artisan cannot determine what additional or material limitations are placed upon a claim by the presence of this element. The metes and  
10 bounds are not clearly set forth. It is suggested that the claim recite "bone morphogenetic protein."

**New Formal Matters, Objections, and/or Rejections:**

***Priority***

15 Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior  
20 nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

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The reference to the 378,537 and 655,579 prior nonprovisional applications does not include the relationship (i.e., continuation, divisional, or continuation-in-part) between the 378,537 and 655,579 and/or between the 378,537 and 655,579 and any other application.

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***Claim Rejections - 35 USC § 112***

Claims 24, 35, 38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claims are directed to or encompass naturally occurring allelic variants. Allelic or other variations of the sequences of FIGS. 1 through 3, whether such nucleotide changes result in changes in the peptide sequence or not, are also included in the present invention (the present specification at page 4, lines 29-32). However, the specification does not provide any particular definition for the term allele. In this circumstance, the meaning of the term is the ordinary usage in the art. The ordinary meaning of the term allele is one of two or more alternate forms of a gene occupying the same locus on homologous chromosomes. See, Lodish (U), page G-1. The specification discloses only one allele within the scope of the genus: the nucleotide and amino acid sequence of figure 2. However, there is no description of the mutational sites that exist in nature, and there is no description of how the sequences in Figure 2 relate to the structure of any allele. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles. The nature of alleles is that

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they are variant structures, and in the present state of the art the structure of one does not provide guidance to the structure of others. The common attributes of the genus are not described. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Claims 33, 36, 39, 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to or encompass a DNA molecule that hybridizes to the sense strand of Figure 2 and encodes a BMP. However, such a DNA molecule is antisense to BMP encoding DNA and does not encode anything within the current application's meaning of a BMP. Accordingly, the present specification has not told the skilled artisan how to make a DNA molecule encoding a BMP that is encoded by an antisense DNA molecule and/or the present specification has not told the skilled artisan how to use a protein encoded by an antisense DNA molecule as a BMP. Given the limited amount of direction and working examples provided by the inventor regarding BMP encoding DNA molecules, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

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***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

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Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5            Claims 24-26, 29, 30, 33, 42 are rejected under 35 U.S.C. 101 because the claimed  
invention is directed to non-statutory subject matter. A DNA sequence is not patentable because  
a sequence is merely descriptive of the linear order of monomers of which the DNA molecule is  
made and is not a "composition of matter." An isolated and purified DNA molecule may be  
patentable because a molecule is a "composition of matter," one of the four classes of invention  
10 authorized by 35 U.S.C. 101.

**Conclusion**

Claim 41 is objected to the extent that it is directed to a nonelected invention.

15            ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO  
DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH  
FRIDAY FROM 7:30 A.M. TO 4:00 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S  
SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (571) 272-0887.

20            IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO  
THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHT FAX NUMBERS:

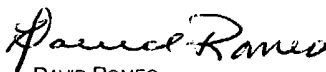
BEFORE FINAL        (703) 872-9306

AFTER FINAL         (703) 872-9307

25            CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL  
OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (571) 273-0890.

30            ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED  
TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.



DAVID ROMEO  
PRIMARY EXAMINER  
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35            DSR  
MAY 15, 2004